510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number
k060351

B. Purpose for Submission:
New device

C. Measurand:
Oxycodone

D. Type of Test:

Qualitative immunoassay, lateral flow immunochromatographic

E. Applicant:
MedTox Diagnostics

F. Proprietary and Established Names:

MedTox Oxycodone

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.3650, Enzyme Immunoassay, Opiates
2. Classification:
   Class II
3. Product Code:
   DJG
4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use below.

2. Indication(s) for use:
   The MEDTOX® OXYCODONE Test System uses immunochromatographic test strips for the rapid, qualitative detection of oxycodone in human urine. It is intended for prescription use.

   The test detects oxycodone at concentrations of 100 ng/mL and above.

The MEDTOX® OXYCODONE assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result.

3. Special condition for use statement(s):
   The MEDTOX® OXYCODONE provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result.

   The assay is intended for prescription use in point-of-care settings.

   Tests for oxycodone cannot distinguish between abused drugs and certain prescribed medications.

   Certain foods or medications may interfere with tests for oxycodone and cause false positive results.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

I. Device Description:

The product is a single-use device in a cassette format. The device includes the immunochromatographic strip enclosed in plastic, a plastic dropper for dispensing urine, and the package insert. At one end is the sample well where the urine sample is applied. The test reaction is initiated by movement of the sample through the test strip. In the middle of the device is a read window with a test line for oxycodone and a control line. Above the read window are interpretations for negative or non-negative for the test line and valid or invalid for the control line.

Description of the test antibody: monoclonal mouse antibody against oxycodone.

Description of the control line antibody: rabbit polyclonal anti-mouse.

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J. Substantial Equivalence Information:

1. Predicate device name(s):

   DRI Oxycodone Assay
2. Predicate 510(k) number(s):
   k040411
3. Comparison with predicate:
   Both devices are for the qualitative determination of the same analyte in the same matrix, and utilize the same cutoff concentration. The predicate uses

liquid reagents on automated clinical chemistry analyzers. The candidate device is visually read and designed for single use only.

The reagent formulations vary between the two devices.

Similarities		
Item	Predicate	Device
Cutoff	Same	100 ng/mL
Cross-reactivity to opiates and oxycodone metabolites other than oxymorphone	Less than 1%	2% or less
Test Antibodies	Same	Mouse monoclonal anti-oxycodone

Differences		
Item	Predicate	Device
Methodology	Automated homogeneous enzyme immunoassay	Lateral flow immunochromatographic
Procedure	Automated	Manual
Controls	Controls must be run separately in the same manner as patient samples	Control provided on each strip
Calibration Required	Yes	No
Cross-reactivity to oxymorphone (primary metabolite)	103%	50%

K. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards in this submission.

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

The sponsor performed two Precision/Reproducibility studies. The first was conducted at the sponsor's facility.

Specimen description: drug free urine spiked with oxycodone
Number of days: three
Replicates per day: two
Lots of product used: one
Number of operators: three
Operator: manufacturer staff
Testing Facility: manufacturer

Results of the study are presented below:

Oxycodone Precision Study Results at Sponsor's Facility

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	54	54/0
25	54	54/0
50	54	50/4
75	54	14/40
100	54	4/50
125	54	1/53
150	54	0/54

The second precision study was performed at three point of care sites.

Specimen description: drug free urine spiked with oxycodone
Number of days: one
Replicates per day: ninety (six concentrations X fifteen replicates per concentration)
Lots of product used: one
Number of operators: nine
Operators: POC staff, DOA Collection Center Staff, Rehabilitation Center Staff
Testing Facilities: Three POC sites

Results of the study are presented below:

Oxycodone Precision Study Results at Point of Care Sites

Concentration of sample, ng/mL	Number of determinations			Results # Neg/ #Pos		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
0	15	15	15	15/0	15/0	15/0
25	15	15	15	15/0	15/0	15/0
50	15	15	15	13/2	15/0	14/1
100	15	15	15	0/15	3/12	3/12
125	15	15	15	0/15	2/13	1/14
150	15	15	15	0/15	0/15	0/15

b. *Linearity/assay reportable range:*
Not applicable. The assay is intended for qualitative use.

c. *Traceability (controls, calibrators, or method):*
External control materials are recommended but are not specifically identified in the labeling.

The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. *Detection limit:*
Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration (100 ng/mL) of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result.

This information appears in the precision section, above.

e. *Analytical specificity:*
Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Drug compound	**Response equivalent to cutoff in ng/mL**	**Percent Cross-Reactivity**
6-monoacetylmorphine	Negative at 100,000	< 1%
Apomorphine	Negative at 100,000	< 1%

Drug compound	Response equivalent to cutoff in ng/mL	Percent Cross-Reactivity
Codeine	5,000	2%
Dihydrocodeine	10,000	1%
Ethylmorphine	5,000	2%
Heroin	Negative at 100,000	< 1%
Hydrocodone	75,000	< 1%
Hydromorphone	50,000	< 1%
Levorphanol	Negative at 50,000	< 1%
Morphine	50,000	< 1%
Morphine-3-β-glucuronide	Negative at 100,000	< 1%
Morphine-6-β-glucuronide	Negative at 100,000	< 1%
Nalorphine	Negative at 100,000	< 1%

Drug compound	Response equivalent to cutoff in ng/mL	Percent Cross-Reactivity
Naloxone	50,000	< 1%
Naltrexone	Negative at 100,000	< 1%
Norcodeine	100,000	< 1%
Oxymorphone	200	50%
Thebaine	Negative at 100,000	< 1%

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor prepared two control samples that consisted of drug-free urine spiked with 25 ng/mL (to test for positive interference) and 150 ng/mL (to test for negative interference) of oxycodone. Next, 100 µg/mL of all of the potentially interfering compounds were added to separate aliquots of the control samples and analyzed. There were no deviations from the expected results for the following compounds:

Acetylsalicylic Acid
Acetaminophen
Brompheniramine
Caffeine
Carbamazepine
Chlorpheniramine
Cocaine
Doxylamine
Dextromethorphan
5,5 Diphenylhydantoin
Ibuprofen
Phenobarbital
d-Pseudoephedrine
Salicylic Acid

The sponsor did a second interference study which tested for positive interference only. It is noted that these compounds were spiked into drug-free urine (zero concentration oxycodone) only. All of the compounds listed below were spiked in at a concentration of 100 µg/mL with the following exceptions: Alprazolam @ 25 µg/mL, Alprazolam, 1-Hydroxy @ 10 µg/mL, Buprenorphine @ 10 µg/mL, Fentanyl @ 10 µg/mL, 11-hydroxy-Δ^9-THC @ 10 µg/mL, Lorazepam glucuronide @ 10 µg/mL, 11-Nor-9-carboxy Δ^9-THC @10 µg/mL, Olanzapine @ 10 µg/mL, Oxazepam glucuronide @ 10 µg/mL, and Triazolam, 1-hydroxy @ 10 µg/mL. There were no deviations from the expected negative results.

Acecainide
Acetaminophen
Acetylsalicylic Acid
Allobarbital
Alprazolam
Alprazolam, 1-Hydroxy
p-Aminobenzoic Acid
7-Amino-clonazepam
7-Amino-flunitrazepam
Aminoglutethimide
l-Aminopyrine
Amitriptyline
Amobarbital
Amoxapine
Amoxicillin
d-Amphetamine
l-Amphetamine
Ampicillin
Aprobarbital
l-Ascorbic Acid
Aspartame
Atenolol
Atropine Sulfate
Barbital
Barbituric Acid
Benzilic Acid
Benzoic Acid
Benzocaine
Benzoylecgonine
Benzphetamine
Benztropine
Brompheniramine
Buprenorphine
Bupropion
Butabarbital
Butalbital
Caffeine
Cannabidiol
Cannabinol
Captopril
Carbamazepine
Carbamazepine-,11 epoxide
Carisoprodol
Cephalexin
Chloral Hydrate
Chloramphenicol
Chlordiazepoxide
Chloroquine
Chlorothiazide
Chlorpheniramine
Chlorpromazine
Chlorprothixene
Clobazam
Clomipramine
Clonazepam
Clonidine
Clorazepate
Clozapine
Cocaine
Cortisone
Cotinine
Cyclobenzaprine
Cyclopentobarbital
Deoxycorticosterone
Desalkylflurazepam
Desipramine
Norchlordiazepoxide
Desmethylflunitrazepam
Desmethylvenlafl axine
Dexamethasone
Dextromethorphan
Diazepam
Diclofenac
Diethylpropion
Diflunisal
Digoxin
Dimenhydrinate
1,3-Dimethylbarbituric acid
Diphenhydramine
Domperidone
Dopamine
Doxepin
Doxylamine
Ecgonine
Ecgonine Methyl Ester
EDDP
Efavirenz
EMDP
Ephedrine
Equilin
Erythromycin
Estrone
Ethanol
Fenfluramine
Fenoprofen
Fentanyl
Flunitrazepam
Fluoxetine
Lurazepam
Furosemide
Fuvoxamine
Gentisic Acid
Glutethimide
Guaiacol Glyceryl Ether

Haloperidol
Hexobarbital
Hippuric acid
Hydralazine
Hydrochlorothiazide
Hydrocortisone
Hydroxybupropion
Hydroxyhippuric acid
l-11-Hydroxy-Δ^9-THC
p-Hydroxyphenobarbital
4-Hydroxyphencyclidine
3-Hydroxytyramine
Hydroxyzine
Ibuprofen
Imipramine
Iproniazid
(R)-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Lidocaine
Lithium carbonate
Loperamide
Lorazepam
Lorazepam glucuronide
Loxapine
Lysergic Acid
Lysergic Acid Diethylamide
Maprotiline
MDA
MDEA
MDMA
Melanin
Meperidine
Mephobarbital
Mepivacaine
Mesoridazine
Methadone
d-Methamphetamine
l-Methamphetamine
Methaqualone
Methcathinone
Methocarbamol
Methoxyphenamine
Methylphenidate
Methylprylon
Metoprolol
Midazolam
Mirtazapine
Nalidixic Acid
Naproxen
Niacinamide
Nicotine
Nifedipine
Nitrazepam
Nitrofurantoin
Norclomipramine
Nordiazepam
Nordoxepin
Norethindrone
Norlysergic Acid
Normeperidine
Norpropoxyphene
l-Norpseudoephedrine
11-Nor-9-carboxy-Δ^9-THC
11-Nor-9-carboxy-Δ^8-THC
Nortriptyline
Noscapine
Nylidrin
Octopamine
Ofloxacin
Olanzapine
Omeprazole
Orphenadrine
Oxalic Acid
Oxaprosin
Oxazepam
Oxazepam glucuronide
Oxolinic Acid
Oxymetazoline
Papaverine hydrochloride
Penicillin G
Pentazocine
Pentobarbital
Perphenazine
Phenallymal
Phenacetin
Phencyclidine
Phendimetrazine
Phenelzine
Phenethylamine
Pheniramine
Phenmetrazine
Phenobarbital
Phenothiazine
Phentermine
Phentoin
Phenylbutazone
Phenylephrine
Phenylpropanolamine
Piroxicam
Prazosin
Prednisolone
Prednisone
Procaine
Procainamide
Prochlorperazine
Promazine
Promethazine
Propoxyphene
Propranolol
Protriptyline
d-Pseudoephedrine
Pyrilamine
Quetiapine
Quinidine
Ranitidine
Riboflavin
Rifampin
Salicylic Acid
Secobarbital
Selegiline
Serotonin
Sertraline
Sildenafil
Sulfamethazine
Sulindac
Talbutal
Temazepam
Tetracycline
Δ^9-Tetrahydrocannabinol
Δ^8-Tetrahydrocannabinol
Tetrahydrozoline
Theophylline
Thiamine
Thiopental

Thioridazine	Triazolam, 1-	Tryptophan
Thiothixine	hydroxy	Tyramine
Tolbutamide	Trifluoperazine	Tyrosine
Tolmetin	Trimethoprim	Valproic Acid
Trazodone	Trimipramine	Venlafaxine
Triamterene	Tripelennamine	Verapamil
Triazolam	Tryptamine	Zomepirac

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

To test for potential positive/and or negative interference from endogenous conditions the sponsor performed the following studies:

To assess the effects of pH on the assay, the sponsor prepared samples from a pH of 4-9 and then to separate aliquots spiked in oxycodone at concentrations of 25 and 150 ng/mL. There were no deviations from the expected results.

The sponsor did a similar study with specific gravity values of 1.003, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, and 1.035 with urine samples spiked at 25 and 150 ng/mL. There were no deviations from the expected results.

For other endogenous substances, the sponsor performed a study which tested for positive interference only. It is noted that these compounds were spiked into drug-free urine (zero concentration oxycodone) only. The following table lists the compounds, the concentration that was spiked into drug-free urine, and the result.

Compound	**Concentration**	**MEDTOX Oxycodone result**
Acetaldehyde	100 µg/ml	NEG
Acetone	100 µg/ml	NEG
Albumin, human	20 mg/ml	NEG
Bilirubin	200 µg/ml	NEG
Cholesterol	100 µg/ml	NEG
Creatinine	100 µg/ml	NEG
d,l-Thyroxin	100 µg/ml	NEG
Epinephrine	100 µg/ml	NEG
B-Estradiol	100 µg/ml	NEG
Estriol	100 µg/ml	NEG
Glucose, Standard Solution	100 µg/ml	NEG
Hemoglobin, human	100 µg/ml	NEG
Sodium Chloride	100 µg/ml	NEG

Compound	Concentration	MEDTOX Oxycodone result
Tetra hydrocortisone	100 µg/ml	NEG
Uric Acid	100 µg/ml	NEG

f. Assay cut-off:
The Substance Abuse and Mental Health Services Administration (SAMHSA) has not recommended a cutoff concentration for oxycodone. The sponsor's claimed cutoff is 100 ng/mL.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. Method comparison with predicate device:
The candidate device was compared both to a reference method, GC/MS, and to the predicate device.

A total of 161 samples (116 negative and 45 positive) were evaluated by the candidate device and by GC/MS and/or the predicate device.

Sample description: Unaltered clinical urine samples were evaluated. 37 additional diluted samples were also included in the study. The samples were prepared by diluting clinical samples with high drug concentrations with drug-free urine. This was done in order to obtain samples near the cutoff concentration of the assay, because the sponsor was not able to obtain unaltered samples near the cutoff.

Sample selection: Samples previously analyzed by the predicate device were selected to be analyzed by the candidate device. Samples were chosen for the study based on whether they screened positive or negative by the predicate device.

Only those samples found positive by the predicate device were analyzed by GC/MS. A portion of samples having drug concentrations that were below the cutoff concentration of the assay were also evaluated by GC/MS.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration

Number of study sites: three
Type of study site(s): POC setting

Operator description: POC staff, DOA Collection Center Staff, Rehabilitation Center Staff

Candidate Device Results vs. stratified GC/MS Values

Candidate Device Results	**Negative** by Immunoassay Predicate Device	**Concentration** of up to the cutoff -50%	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	2	2	6	37
Negative	103	5	4	1	1

GC/MS values used to categorize samples in this table are determined by adding together the concentration of oxycodone plus 50% of the concentration of oxymorphone, based on the sponsor's cross-reactivity studies.

% Agreement among positives is 96%
% Agreement among negatives is 97%

The sponsor also performed a method comparison study at their own facility using many of the same samples as in the POC study above. Results between the two studies were similar.

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision**.**